

**International Conference on Harmonization (ICH)**  
**M2 EWG Meeting - Summary**  
**Brussels, 08 March to 11 March 1999**

---

Participants:

**EU:** Esteban Gonzalez Juarros, Jörg Lekschas, Thomas Lönngren, Stan van Belkum  
**EFPIA:** Gabriele Disselhoff, Marc Elbet (partly), Andrew Marr, Mervyn Mitchard (partly),  
**PhRMA:** Kris Arora, Bob Hizer  
**FDA:** Greg Brolund (Rapporteur), Melissa Chapman, George P George, Robin Jones  
**JPMA:** Hitoshi Asano, Yuichi Nagoshi, ,Tohru Uwoi, Harv Martens  
**MHW:** Daisuke Koide, Junji Yamamoto, (partly), Yoko Nakamura (partly), Mihoko Okada  
**Observer:** Bob Kapitany

The tasks accomplished and the decisions agreed are the following:

1. The “Electronic Transmission of Individual Case Safety Reports Message Specification” including the ICH ICSR DTD Version 2.0 was signed by all six parties and the observer as the final document of the EWG. The ICH SC decided to sign the document during their next meeting in Washington in October 1999.

2. Specification for the Electronic CTD (eCTD)

The EWG have

- ◆ agreed on the scope document for the eCTD reflecting the content of the Concept Paper
- ◆ begun writing a functional requirements document to facilitate understanding of the requirements among all ICH parties
- ◆ presented their process of developing the eCTD to the CTD co-ordination group
- ◆ presented status and results to the SC and have had the assumptions endorsed that the eCTD specification will apply to
  - ◆ the entire dossier
  - ◆ variations and amendments as well as the original submission.
- ◆ agreed to clarify the functional requirements and decided to comment on this document through one contact point for regulators (Greg Brolund) and one for industry (Bob Hizer)
- ◆ agreed on having the next draft of the functional requirements document in July 1999 and provide it to the CTD EWGs and ask for comments by the October 1999 SC meeting.

The next M2 meeting will take place in Washington DC, from October 4 - 7, 1999, as proposed for the ICH Steering Committee meeting.